

**UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.**

In the Matter of

**CERTAIN DENTAL AND
ORTHODONTIC SCANNERS AND
SOFTWARE**

Investigation No. 337-TA-1144

**NOTICE OF THE COMMISSION'S FINAL DETERMINATION FINDING NO
VIOLATION OF SECTION 337; TERMINATION OF THE INVESTIGATION**

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has found no violation of section 337 of the Tariff Act of 1930, as amended. The investigation is hereby terminated.

FOR FURTHER INFORMATION CONTACT: Robert Needham, Office of the General Counsel, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 708-5468. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 205-2000. General information concerning the Commission may also be obtained by accessing its Internet server (<http://www.usitc.gov>). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at <http://edis.usitc.gov>. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205-1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on March 5, 2019. 84 FR 7933-34 (March 5, 2019) based on a complaint filed on behalf of Align Technology, Inc. of San Jose, California ("Align"). The complaint alleges violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain dental and orthodontic scanners and software by reason of infringement of one or more claims of U.S. Patent Nos. 9,299,192 ("the '192 patent"); 7,077,647 ("the '647 patent"); 7,156,661 ("the '661 patent"); 9,848,958 ("the '958 patent"); and 8,102,538 ("the '538 patent"). *Id.* The complaint further alleges that a domestic industry exists. *Id.* The Commission's notice of investigation named as respondents 3Shape A/S of Copenhagen, Denmark; 3Shape, Inc. of Warren, New Jersey; and 3Shape Trios A/S of Copenhagen, Denmark (together, "3Shape"). *Id.* The Office of Unfair Import Investigations is not participating in the investigation. *Id.*

The Commission subsequently terminated the investigation with respect to the '958 patent based on Align's withdrawal of those complaint allegations. Order No. 17 (Jul. 2, 2019), *not reviewed* Notice (Jul. 23, 2019). On October 8, 2019, Align stated that it would no longer pursue a violation with respect to claims 4 and 20 of the '647 patent, claims 1 and 19 of the '661 patent, and claims 1, 3-5, and 22 of the '192 patent. On October 21, 2019, Align stated that it would no longer pursue a violation with respect to claim 2 of the '647 patent. Accordingly, at the time of the Final ID, Align asserted claims 1 and 18 of the '647 patent, claims 2 and 20 of the '661 patent, claims 1 and 2 of the '538 patent, and claims 2, 28, and 29 of the '192 patent.

On April 30, 2020, the ALJ issued the Final ID finding a violation of section 337 with respect to the '647 and '661 patents, and no violation with respect to the '538 and '192 patents. Specifically, the ALJ found that claims 1 and 18 of the '538 patent are not infringed and that claims 2, 28, and 29 of the '192 patent are invalid. The ALJ found that Align satisfied the remaining requirements for a violation with respect to the '538 and '192 patents.

On May 12, 2020, 3Shape and Align each filed a petition for review of the Final ID. On May 20, 2020, the parties responded to each other's petitions. The Commission also received four comments on the public interest.

On January 31, 2020, the Commission determined to review the Final ID in part. Specifically, the Commission determined to review the following issues: (1) the findings regarding importation and induced infringement; (2) the construction of limitation 1.5/18.5 of the '647 patent ("individually matching [match] each of the dental objects in the subsequent digital model with a dental object in the initial digital model to determine corresponding dental objects, the matching comprising [including instructions to]") in the asserted claims of the '647 patent, and the application of that construction regarding infringement, invalidity, and the technical prong of the domestic industry; (3) the findings regarding whether the asserted claims of the '647 and '661 patents are directed to patentable subject matter; (4) the construction of the limitation "wherein the device is configured for maintaining a spatial disposition with respect to the portion that is substantially fixed during operation of the optical scanner and imaging means" in the asserted claims of the '538 patent, and the application of that construction regarding infringement, invalidity, and the technical prong of the domestic industry requirement; (5) the findings regarding whether Okamoto anticipates the asserted claims of the '538 patent; (6) the findings regarding whether Paley-Kriveshko anticipates or renders obvious the asserted claims of the '192 patent; and (7) the findings regarding the satisfaction of the economic prong of the domestic industry requirement.

Having examined the record of this investigation, including the Final ID, the petitions, responses, and other submissions from the parties, the Commission has determined that Align has failed to show a violation of section 337. Specifically, the Commission has determined to: (1) modify the Final ID's findings on importation; (2) reverse the Final ID's finding that Align showed induced infringement for the '647 and '661 patents; (3) modify the Final ID's interpretation of the limitation "to determine corresponding dental objects" in the asserted claims of the '647 patent, but find that the modification does not affect the application of the construction to infringement, the domestic industry, or invalidity; (4) take no position on the Final ID's finding that the asserted claims of the '647 and '661 patents are directed to patentable

subject matter; (5) modify the ALJ's construction of "wherein the device is configured for maintaining a spatial disposition with respect to the portion that is substantially fixed during operation of the optical scanner and the imaging means" of the asserted claims of the '538 patent, and find that, under the modified construction, Align established infringement and the technical prong of the domestic industry requirement but that the asserted claims are invalid; (6) reverse the Final ID's finding that the asserted claims of the '538 patent are not anticipated by Okamoto; (7) reverse the Final ID's finding that the asserted claims of the '192 patent are not anticipated by Paley-Kriveshko, and affirm the Final ID's finding that the asserted claims are invalid as obvious under modified reasoning; and (8) take no position on whether Align satisfied the economic prong of the domestic industry requirement.

Accordingly, the Commission finds no violation of section 337. Specifically, the Commission finds that Align failed to establish a violation with respect to the asserted claims of the '647 and '661 patents because Align failed to show infringement; that Align failed to establish a violation with respect to the asserted claims of the '538 patent because Align failed to show infringement and because the claims are invalid; and that Align failed to establish a violation with respect to the asserted claims of the '192 patent because the claims are invalid. The Commission's determinations are explained more fully in the accompanying Opinion. All other findings in the ID under review that are consistent with the Commission's determinations are affirmed. The investigation is hereby terminated.

The Commission vote for these determinations took place on November 17, 2020.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.



Lisa R. Barton
Secretary to the Commission

Issued: November 17, 2020